

Information Notice

Medical Devices

HIV Self-tests

CE Mark

Notified Body
Number

XXXX

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ISSUE

Human Immunodeficiency Virus (HIV) is a virus that attacks the human immune system and weakens its ability to fight infection and disease. Early treatment of HIV keeps the immune system strong and prevents illness. Potential ways in which you might be exposed to HIV and be a risk of infection are explained on the HSE's [Sexual Wellbeing](#) website. Untreated HIV can lead to a number of serious conditions. The earlier the virus is detected, and treatment is commenced, the better.

With the increased availability of CE marked HIV self-tests on the European market, such tests will likely become more widely available in Ireland through pharmacies and internet sales. The purpose of this information notice is to provide advice for people who are thinking about buying a HIV self-test and to highlight some key considerations when sourcing and using HIV self-tests.

Early, appropriate, treatment of HIV is critical; so if you get a positive result from a self-test for HIV, or if you get a negative result and you are still concerned about a potential exposure to HIV you should urgently seek assistance from your GP or a Sexual Health Clinic (see below for further details).

Background

HIV self-tests are classified as *in-vitro* diagnostic medical devices. Many types of self-tests are now available e.g. HIV self-tests, pregnancy self-tests and blood glucose monitoring test kits. Self-tests can be used to diagnose a variety of conditions or to monitor a particular condition or response to treatment. HIV self-tests providing a result in minutes to the user directly. They can be purchased from many different sources including pharmacies and online.

While self-tests have a role to play in a healthcare setting, they should not be relied upon in isolation and it is important to remember that if a person has any concerns about their health or a HIV self-test result they should consult an appropriate health care professional.

There are a number of different ways to test for HIV Infection which normally require a blood sample, although some use other samples such as saliva. It is important to be aware of the difference in these tests:

Self-Testing – This is carried out by the person themselves following the manufacturer's instructions. HIV self-tests are tests which can be carried out at home.

Rapid HIV Tests (also called point of care or near patient tests) are available and provide results within minutes but are normally used within a healthcare setting.

Home sampling - Some tests involve home sampling, where a user self-samples and sends the sample to a laboratory for testing.

Laboratory Testing – The most accurate test available for HIV is a laboratory based confirmatory test. Laboratory based HIV testing is available in many health care settings including Sexually Transmitted Infection (STI) clinics, genito-urinary medicine (GUM) clinics, General Practitioners (GPs), Non-Governmental Organisations (NGOs) and Student Health Clinics.

All STI testing in public sexual health or GUM (genito-urinary medicine) clinics is provided free of charge. [Click here for a list of public STI services available](#). STI testing is also available through many GPs, NGOs or student health services for a fee. NGO's who provide HIV testing are listed on the [HIV Services Ireland](#) website.

Considerations for users purchasing/using a HIV self-test or home sampling test:

- **Check the test is CE marked** - A valid HIV self-test bears a CE mark and a four digit number (refer to the image above) to confirm it meets important safety and design standards. This four digit number will be displayed below the CE mark and indicates the test has been assessed by an independent body in accordance with European law.
- **Check there is a European address on the packaging** - Medical devices that are CE marked and sold on the European market must have a registered business premises in Europe.
- **Source the test from a reputable source** - HIV self-tests should always be purchased from a reliable source e.g. pharmacy or directly from the manufacturer or authorised distributor. Particular care should be taken when purchasing HIV self-tests online.
- **Read the instructions** - A number of factors may interfere with or affect test results e.g. length of time from exposure to when the virus/infection may be detectable. It is important to ensure you always read the instructions carefully to see how the result may be impacted and what the limitations of the test are.
- **Check the packaging** - Before using the test, make sure that the packaging is not damaged and that any seals are intact. Check the expiry date on the packaging and do not use the test if it is out of date.
- **Prepare for the test** - Ensure you have everything required to carry out the test before you start e.g. timer/stopwatch. Ensure you know how to interpret the test result by reading the instructions carefully before you begin.

Important Information

- No HIV self-test can detect HIV immediately after infection. If you think you have been exposed to HIV in the previous 72 hours, you should go to your nearest STI/GUM (genitourinary medicine) clinic or hospital emergency department as soon as possible to see if you need to go on HIV post-exposure prophylaxis (PEP). PEP is a course of medication that needs to be started as soon as possible and at least within 72 hours after you have been exposed to HIV. PEP can reduce your chances of becoming HIV positive. Further information on HIV PEP and where it can be accessed is available on the [HSE's sexualwellbeing.ie website](http://www.sexualwellbeing.ie).
- When using a HIV self-test it is important to know the window period for the test. The time between when a person may have been exposed to HIV and when a test can detect if they have HIV is called the *window period*. The window period varies from person to person and depends on the test used.
- Most HIV self-tests (antibody tests) have a window period of 3 months following exposure to HIV. This is the length of time it can take for a sufficient quantity of antibodies to be produced in order to be detected by the HIV self-test. During the window period a person can be infected with HIV but still have a negative HIV test.
- Therefore, the use of HIV self-tests are normally only reliable 3 months after the potential exposure to HIV. Use of these tests before the manufacturer's recommended time after exposure to HIV could result in false negative results and failure to detect HIV as the test may not reliably detect HIV prior to that time.
- If you are being treated for HIV with antiretroviral therapy (ART) or you are taking pre-exposure prophylaxis (PrEP), it is important that you are monitored by your doctor for HIV, other STIs and side effects of PrEP. HIV self-tests are not appropriate for people already diagnosed with HIV or for people taking PrEP as they are not a reliable way to monitor these situations.
- Further guidance on PrEP is available from the [Health Protection Surveillance Centre \(HPSC\) website](http://www.hpsc.ie).
- Always refer to the manufacturer's instructions for use for specific details. There are other HIV tests available that have a shorter window period. Talk to your healthcare provider about available options.
- Remember that no test is 100% reliable.
- Regardless of the result, we recommend you consult a doctor if you have any concerns about your health or a positive/negative test result.

Available Information and Support services for Patients

- HSE website - <http://www.sexualwellbeing.ie>
- HSE HIV Helpline - Confidential freephone helpline on 1800 459 459 from Monday to Friday between 9:30 am and 5:30 pm

- Health Protection Surveillance Centre (HPSC) website <http://www.hpsc.ie>
- STI Testing Services in Ireland
 - Public STI testing: <https://www.sexualwellbeing.ie/>
 - NGO's providing testing: <http://www.hivservices.ie/>

RECOMMENDATIONS

The HPRA advises that users:

- 1 Purchase medical devices from reputable sources. Try to buy directly from pharmacies or from the manufacturer or authorised distributor.
- 2 Ensure that HIV self-tests bear a CE mark and have a notified body (4 digit) number affixed.
- 3 Look for a European address on the packaging - medical devices that are CE marked and sold on the European market must have a registered business premises in Europe.
- 4 If you get a positive result from a HIV Self-Test, or you get a negative result and are still concerned about a potential exposure to HIV, you should urgently seek assistance from your GP or a Sexual Health Clinic.
- 5 Consult your healthcare provider if you have any concerns about your health or a test result.
- 6 Regardless of the result, always carry out follow up testing with your healthcare provider.
- 7 Consider the potential exposure time and talk to your healthcare provider as soon as you can about the most appropriate test for you.
- 8 For further information, see the HPRA's published consumer advice leaflets: [Self-text products](#) and [Purchasing medical devices online](#).
- 9 Report any unexpected problems or malfunctions to the manufacturer of the device. Incidents that may affect an individual's health or cause or contribute to an injury can also be reported directly to the HPRA via our [online user report form](#).
- 10 Contact the HPRA using the details below if you have concerns regarding a specific test or product.

HPRA CONTACT INFORMATION

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